Operation Iraqi Freedom Depleted Uranium (DU) Medical Management Supplemental Information (Clinical Guidance) to ASD Memorandum, Operation Iraqi Freedom Depleted Uranium Medical Management, 9 Apr 04

1. Identification and Assessment of DU-Exposed Personnel.

a. Reactive and proactive identification. There are two primary methods of identification of personnel potentially exposed to DU: proactive and reactive.

Proactive: The Services have been directed to identify units and the personnel assigned to units that could have been exposed to DU using information about events involving DU munitions or other DU containing materials that may have resulted in internal exposure to DU. Identification of members in these groups and detailed descriptions of the possible exposure conditions provide valuable information for verifying that potentially exposed individuals are being identified and evaluated.

Reactive: The majority of personnel are most likely to be identified by reactive methods through individual self-report. These methods would include a positive response to Questions 14, 17, and 18 of the DD Form 2796, Post Deployment Health Assessment (PDHA); through self-report of patients to operational medical assets in-theater; through self-report or clinical reports of patients entered into the air-evacuation system for either DU wounds or other medical reasons; and through self-report of patients to primary care under the Post-Deployment Health Evaluation and Management Clinical Practice Guideline (PDH-CPG).

b. Assessment. Healthcare providers will complete the DoD DU Questionnaire and Health Survey along with the individuals being assessed for DU exposure. These forms are currently available as DoD Test Forms (DD Form 2872 Test and DD Form 2872-1 Test). In the near future these two test forms will be overprinted on a single Standard Form SF-600. These forms can be downloaded from the DoD Deployment Health Clinical Center (DHCC) website, www.pdhealth.mil. The healthcare provider along with the individuals being evaluated will review the DoD DU Questionnaire and any other supporting information. Individuals considered to be possibly exposed to DU will be assigned by the healthcare provider to one of the three DU exposure categories, either level I, II, or III.

Level I: This exposure level is assigned to all individuals who were believed to be struck by DU munitions or DU armor fragments. In addition, it includes those who were in, on, or less than 50 meters from an armored vehicle at the time it was struck by munitions believed to contain DU and to first responders who entered these vehicles to render aid to the crewmen. These personnel may exceed peacetime standards for internal exposures to DU. Urine DU bioassays are required for all personnel within this exposure level. For hospitalized Level I patients, bioassays are to be administered on a priority basis as soon as their medical condition permits collection of a complete 24-hour urine sample. Other Level I personnel will have bioassays performed as soon as possible, even if the most ideal testing period, within 180 days post-exposure, has been exceeded.

Level II: This exposure level is assigned to those personnel, other than first responders, who routinely entered vehicles possibly containing DU residues to perform

maintenance and recovery operations, intelligence operations, or battle-damage assessments. This exposure level also includes individuals whose occupation required them to fight fires involving DU-containing materials. Personnel in this level may exceed peacetime standards for occupational exposures to DU. Urine DU bioassays are required for all personnel with this level of exposure; the bioassays should be performed as soon as possible, even if the most ideal testing period, within 180 days post-exposure, has been exceeded.

Level III: Level III exposures are those which are incidental in nature. Incidental DU exposures would not likely result in any significant uptake of DU into the body. Examples of Level III exposures include infrequently and only for short periods entering or climbing on or into battle-damaged vehicles or breathing smoke from fires involving DU materials. Bioassays are not required for personnel in this level, though a physician may choose to perform one based on medical indications or on potentially exposed individual's request.

The original copies of the completed DU Questionnaire and Health Survey will be filed in the patient medical record. For those patients warranting further assessment through urine DU bioassay procedures, a Lab Request Tracking Form, contact information for both the patient, the ordering provider, and the Primary Care Manager (or primary care provider at the military treatment facility at the patient's station of assignment), will be forwarded with all urine samples. The laboratory should be contacted for shipping instructions and for information on the requirements for the urine containers (uranium-free). Each laboratory request for urine DU bioassay will include name, SSN, age, sex, height, and weight of the individual; dates of exposure; the date and start and stop times of urine collection. The sample must be identified as an initial 24-hour, initial spot, 7-10 day sample, or a repeat sample. The request should specify that a urine total uranium and uranium isotopic analysis be run and that the results be normalized to urine creatinine with results expresses as nanograms of uranium/gm of urine creatinine, and that results also be normalized to the volume of urine with results expressed as nanograms of uranium per liter of urine. It is permissible for the collecting lab to do the urine creatinine test if they have the capability. In this case, those results must be forwarded along with the urine specimen. Isotopic analysis is the specific test used to identify the fraction of the urine uranium is contributed by DU. Copies of all the exposure assessment and health survey forms must accompany the urine samples.

All forms are available at www.pdhealth.mil. The recipient of those samples and forms, including the Service Labs and Baltimore VA Lab, will forward copies of all completed questionnaires and forms to the DHCC for inclusion in the DoD Depleted Uranium case management system. DHCC and Baltimore VA contact information is included in Appendix B.

2. Urine DU Bioassay Procedures

a. Testing for servicemembers in-theater greater than 180 days post-exposure. HA Policy 03-12 directs collection of urine specimens for uranium testing within 180 days of a potential exposure incident. Every effort should be employed to identify and evaluate personnel who may have been exposed to depleted uranium throughout the deployment cycle according to this guidance. Testing within the 180-day window

increases ability to detect lower level exposures. Nevertheless, urine excretion of uranium continues after the 180 days, and collection of urine samples for initial evaluation of depleted uranium exposure should be accomplished even when the earliest possible testing opportunity presents after the recommended 180-day period.

b. Health Risk Communications. Healthcare providers are responsible for ensuring appropriate health risk communications to patients presenting with DU concerns. Patients will be informed of the reason they are being evaluated for DU, the timelines and nature of the assessment process, the potential individual risk or likelihood of identification of DU exposure, the generally low incidence of significant DU exposure in theater, and the medical follow-up that is available. Providers should demonstrate awareness of potential concerns that patients have regarding potential DU exposure and should communicate, both in content and process, information that will ensure that patients are fully informed and are reassured about the process and potential outcomes. For guidance on effective risk communication procedures, providers are directed to contact Service-designated subject matter experts, the DHCC, or the VA DU Follow-up Program staff included at Appendix B.

c. Sample handling. Urinalysis for the presence of DU constitutes one component in the evaluation of potential exposure to depleted uranium; and the results provide an indicator of the need for further medical follow-up. For both urinary creatinine and uranium testing, each Service is directed to develop processes for collecting, tracking, shipping, and processing samples, reporting results to patients and providers, and ensuring that all pertinent documentation is forwarded to DHCC for entry into the case management system. Services will establish their processes and procedures, and ensure clinical and lab personnel comply with standardized processes and procedures. Care must be taken to ensure that urine specimen containers are free of uranium contamination. Testing laboratories be contacted for information regarding the type of container to use.

d. Laboratory procedures, quality assurance and quality control. Several analytical methods are available for determining the isotopic uranium content in urine. Isotopic analysis is necessary to determine whether any uranium detected in the urine is entirely natural uranium or has a depleted uranium component. Based on experience from evaluating depleted uranium exposures in Operation Desert Storm, analysis of uranium-235 and uranium-238, are indicated and are best-performed using mass spectrometry, generally Inductively Coupled Plasma – Mass Spectrometers that deliver adequate sensitivity.

Accurate and reliable analytical results are vitally important for the uranium assessments. Laboratories performing the analyses must have documented calibration and quality assurance programs for demonstrating reliable performance. In addition, the laboratories should validate internal quality assurance results by participating in intercomparison programs or similar evaluations in collaboration with qualified, independent laboratories. Documentation of all quality assurance activities must be maintained and made available for review by oversight agencies, such as the Deployment Health Support Directorate. Copies of all such documentation will be sent to the Deployment Health Support Directorate, when requested.

3. Results Reporting and Records Management.

a. Results reporting for active duty members. The processing lab will forward results of the urine DU bioassay to the patient's primary care manager or referring provider, as indicated on lab request and specimen tracking form. All positive tests, except those for personnel with embedded DU fragments will require a confirmatory 24-hour sample collection. Along with the lab results, the PCM/primary care provider will receive a letter with further information, including interpretation and health risk communication guidance in communicating results to those providing the urine specimens. In addition, the PCM/primary care provider will be instructed to contact a subject matter expert (SME) at the processing lab for further guidance on interpretation and presentation of results to the patient. Following consultation with DHCC for those Level I and Level II exposures that have positive DU results, DHCC will provide authorization to contact the Baltimore VA to arrange for referral for those whom referral is indicated (see Appendix A).

The PCM/primary care provider will be responsible for providing detailed results to the patient. In addition, a letter may be forwarded directly to the patient by the processing lab indicating that the lab results are available. The PCM/primary care provider will deliver results to the patient using the appropriate health risk communication guidance included in HA Policy 03-12 and also available on the DHCC website, www.pdhealth.mil. The PCM/primary care provider will document delivery of the results in the medical record, ensure that the lab results are filed in the medical record, and make arrangements for referral for follow-up care, as necessary.

b. Results reporting for reserve component (RC) personnel. The processing labs will forward results of the uranium urine bioassay to DHCC. DHCC will contact the servicemember's unit to make arrangements for forwarding and filing the results in the patient's military health system record.

Following release from active duty, RC personnel are eligible for health care services in the VA health Care system for 2 years, with on-going care available for service-related health issues. RC personnel are also eligible to be recalled to active duty to complete required medical care. For RC personnel, DHCC will provide results to servicemembers. For negative bioassays, results will be provided by phone. For positive results (and for negative results, depending on patient needs), servicemembers will be offered the opportunity to meet with a healthcare provider for a follow-up visit to discuss the results. DHCC case managers will facilitate arrangement for a provider visit in a military treatment facility or a VA Medical Center in collaboration with the patient and their unit of assignment.

4. Medical Management.

Agreements have been reached concerning collection of information about exposures and assessment of personnel for medical follow-up in the VA-Baltimore DU Follow-Up Program.

a. Baltimore VA DU Follow-up Program. In reviewing results of the evaluation and urinalysis for possible enrollment in the VA follow-up program, providers will refer to the Protocol for DU Urine Validation Testing and Referrals to the Baltimore VA Follow-up Program at Appendix A. Patients with confirmed positive urine DU bioassays results for DU, as defined in the attached protocol, will be referred to the Baltimore VA DU Follow-up Program following contact with DHCC.

The patient will consult with PCM and with command personnel to determine timing and procedures for attendance in the VA Program. Operational considerations will take precedence in determining program attendance, but initial follow-up should begin NLT six months post-identification. Enrollment in the VA DU Follow-up Program consists of an initial 2.5-day inpatient evaluation. Patients will be offered follow-on services for on-going assessment and medical management based on the outcome of the initial assessment. Continued follow-up program attendance is recommended every two years.

Servicemembers will be referred to the VA Program through completion of a SF513, Consultation Form, a copy of which will be maintained in the medical record. Upon completion of services by the VA, documentation of services provided to the patient will be recorded on the SF513 and through narrative summary and will be provided to the referring provider for inclusion in the medical record and to DHCC for patient case management and archiving.

Funding for participation in the Baltimore VA program, including TDY costs, will be the Services' responsibility.

b. Military Health System Continuing Medical Management. Servicemembers with positive DU exposures, as determined by urine DU bioassays, historically have been asymptomatic. Periodic assessment and medical management will be provided through the VA Program at 2-year intervals. The military health system will continue to provide on-going medical management for servicemember health concerns through standard primary care services following the Post-Deployment Health Evaluation and Management Clinical Practice Guideline. In addition, reported health concerns and progress of care through the VA Program will be assessed during regularly scheduled Periodic/Preventive Health Assessments and Physical Exams.

5. Surveillance and Tracking.

The Services will establish procedures to collect, maintain, and track details of all personnel potentially exposed to DU, the results of their evaluations, and any medical follow-up. Information on exposure conditions will be collected and maintained in sufficient detail to fully characterize the exposure for use in follow-on investigations, evaluations, and health risk assessments. That information should be compared with servicemembers identified with incidents, reports of duties involving possible contact

with DU-contaminated equipment or facilities, and other methods to assure appropriate evaluations are being performed.

6. Archiving and Case Management.

DHCC will provide a central archive for all patient information related to DU exposure, testing, and follow-up for both active duty and reserve component personnel. Assessment questionnaires, lab results, referral consults, and narrative summaries from follow-up care will be forwarded to DHCC for archiving. Service Labs and the Baltimore VA will forward all DU health care documentation to DHCC for archiving following completion of DU-related health services.

Appendix A

Protocol for Urine DU Bioassay Validation Testing and Referrals to the Baltimore VA Follow-up Program

24-Hour Urine Samples

1. If urine [total U] is < 50 ng/g creatinine (cre) **and** isotopic analysis indicates presence of DU with or without evidence of embedded fragments, then repeat urine analysis in 6 months.

2. If urine [total U] is < 50 ng/g cre **and** isotopic analysis does not indicate presence of DU, then no follow-up is necessary.

3. If urine [total U] is ≥ 50 ng/g cre **or** isotopic analysis indicates the sample contains DU at 10% or more, then perform urine uranium analysis on a repeat 24-hr urine sample for confirmation.

   a. If second urine [total U] is still ≥50 ng/g cre **or** isotopic analysis indicates presence of 10% or more DU, then complete a radiological skeletal survey to look for evidence of embedded fragments.

   b. If there is no evidence of embedded fragments on the radiological skeletal survey, then repeat urine DU analysis in 6 months. If still positive after 6 months, the primary care manager first consults with DHCC and, if appropriate, contacts the Baltimore VA for follow-up care.

4. If a servicemember has embedded fragments or fragment-type injuries **and** a urine [total U] ≥ 50 ng/g cre **and** isotopic analysis indicates the presence of DU at 10% or more, primary care manager refers patient to the Baltimore VA In-Patient DU Follow-up Program after consulting DHCC.

Note: all creatinine values used in the calculations to normalize results are urine creatinine concentrations.

Spot Urine Samples

Follow all spot samples with [Total U] ≥ 25ng/g cre with a 24-hour urine test and interpret as above. No follow-up is required for samples with results where [Total U] is < 25 ng/g cre.

Appendix B

DHCC Archiving and Consultation Information

DoD Deployment Health Clinical Center (DHCC) medical staff members are available to discuss DU evaluation and management, archiving, case management procedures, including referral to the Baltimore VA, and to provide forms and documents. In additional, all documentation should be forwarded to DHCC, either in hard or electronic copy. Contact information is:

DoD Deployment Health Clinical Center
Walter Reed Army Medical Center
6900 Georgia Avenue, NW
Bldg 2, Rm 3G04
Washington, DC 20307-5001

Clinician Helpline: 1- 866-559-1627
Toll-free from Europe: 00800-8666-8666
Phone: 202-782-6563
DSN: 662-6563
Fax: 202-782-3539
Email: pdhealth@na.amedd.army.mil
Website: www.pdhealth.mil

Baltimore VA DU Medical Follow-up Consultation and Referral Information

The VA medical staff is available to discuss the management of any patient's case with their clinician to provide guidance in follow-up decisions and discussions with the patients. Contact Information is:

Depleted Uranium Follow-up Program
Baltimore VA Medical Center (11DU)
10 N. Greene Street
Baltimore, MD 21201
1-800-815-7533